

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claims 1-16, 18, 25-26, 45-46, 62-63, 68 and 82-99 were cancelled previously. No claim amendments are made in this response. Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are pending.

II. Rejection of Claims under 35 U.S.C. §103(a)

A. Wiedmann and Saidi

Claims 17, 19-24, 28-44, 47, 49-61, 64-67, 69 and 71-81 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,747,001 to Wiedmann et al. (“Wiedmann”) in view of U.S. Patent No. 6,241,969 to Saidi et al. (“Saidi”). Applicants respectfully traverse the rejection.

The claimed invention relates to a sterile filterable *dispersion* comprising, *inter alia*, *fluticasone particles* sufficiently small to pass through a 0.2 µm filter and having a phase selected from the group consisting of a crystalline phase, an amorphous phase and a semi-crystalline phase.

The Examiner expressly acknowledges that “Wiedmann et al. do not teach fluticasone particles or sterile filtration” (Office Action, page 6, line 12). In an attempt to cure the deficiencies of the primary reference, the Examiner cites Saidi for the alleged teaching of sterile filtration of fluticasone particles.

Contrary to the Examiner’s contention, Saidi does not teach sterile filtration of a *dispersion* comprising fluticasone particles but of a *solution* comprising dissolved corticosteroid.

Specifically, Saidi describes that the corticosteroid be *dissolved* in TPGS (a vitamin E derivative) before filtration. *See* abstract and column 5, lines 34-35, 49-53. Examples 1-4 further demonstrate that the corticosteroid *solution* is diluted and then sterilized by passing through a 0.22 micron sterile filter. Saidi also suggests that cosolvents can be included “to increase the solubility of the corticosteroid” (column 5, lines 15-18). As such, Saidi fails to teach sterile filtration of nanoparticulate fluticasone particles to compensate for the deficiencies of Wiedmann.

B. Wood, Saidi and Biggadike

Claims 17, 19-24, 27-44, 47-61, 64-67, and 69-81 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over PCT Publication No. WO 96/25918 by Wood et al. (“Wood”) in view of Saidi, and further in view of U.S. Patent Application Publication No. 2003/0073676 by Biggadike et al. (“Biggadike”). Applicants respectfully traverse the rejection.

Similar to Wiedmann, and as stated by the Examiner, Wood fails to teach sterile filtration of fluticasone particles (Office Action page 10). As discussed *supra*, Saidi does not remedy the acknowledged deficiency of Wood. The Examiner explicitly states in the Office Action that Biggadike is cited for the proposition of solubilizing an ester of fluticasone and increasing solubility of fluticasone esters by a hydroxyl containing organic co-solvating agent. *See* the paragraph bridging pages 10 and 11. Biggadike is not cited for teaching sterile filtration or fluticasone particles. Accordingly, Biggadike also fails to remedy the deficiencies of Weidman, Wood, and Saidi.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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